



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,279	12/20/2001	Ying-Che Huang	2498-105	5744

6449 7590 02/03/2004

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
----------	--------------

1753

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,279

Applicant(s)

HUANG ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12202001 6) ☐ Other:

Specification

1. The abstract should be 150 words or less. MPEP 608.01(b).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, (a) an anode having a working electrode and an anode connector at both ends of the anode, and (b) a cathode having a reference electrode and a cathode connector at both ends of the cathode must be shown or the features canceled from claim 1. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because the sectional views shown in the "(b)" portions of Figures 6, 10, and 11 do not correspond to the sectional lines in the "(a)" portions of the figures. For example, Figure 6(b) shows both electrodes to the right of an insulating spacer layer and underneath the reticular layer. However, Figure 6(a) shows the reticular layer as extending only over a portion of one electrode. Figure 10(b) shows the sides of the electrode substrate to be parallel to the sides of the reticular layer. However, as seen in Figure 10(a) shows the sides of the

Art Unit: 1753

substrate extending beyond the sides of the reticular layer. Also, the sectional lines in Figure 10(a) are at an angle with respect to the bottom edge of the sensor, which suggests that the widths of electrodes would be different than as shown in Figure 10(b). Figure 11(b) shows a layer having a middle reticular portion covering both electrodes. Figure 11(a) shows two reticular portions, at opposing sides of the sensor and each apparently only extending over a single electrode. Figures 12-15 also show inconsistencies between the "(a)" view and the corresponding "(b)" or "(c)" view.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 1-3 are objected to because of the following informality:
 - a) Claim 1, line 16: "exposing" should be -- exposes --;
 - b) Claim 1, line 14: -- , -- should be inserted after "end"; and
 - c) Claim 1, line 19: -- , -- should be inserted before "wherein"
 - d) Claim 2, line 2: -- , -- should be inserted before "or";
 - e) Claim 2, line 2: "protruding" should be -- protrusion --; and
 - f) Claim 3, line 3: -- the -- should be inserted before "same".
5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1, lines 10-12 refer to "said working electrode" and "said reference electrode" however, lines 4-6 actually requires two working electrode (one at each end of the anode) and lines 7-9 requires two reference electrodes (one at each cathode end). So it is not clear which pair of working and reference electrodes are covered by the reaction layer;

b) Claim 1: an anode is a single electrode, yet the claim requires the anode to have two working electrodes (one at each anode end).

c) Claim 1: a cathode is a single electrode, yet the claim requires the cathode to have two reference electrodes (one at each anode end).

c) Claim 1 recites the limitation "the non-reaction area" in line 16. There is insufficient antecedent basis for this limitation in the claim.

d) Claim 1, line 14 refers to "an opening" and "an opening end." It is not clear whether all later references to an opening also encompass the opening end. That is, is the opening

end meant to be distinct from the opening (are there two openings, in effect)? Also, is the opening end located at the edge of the test strip referred to in line 21?

e) Claim 1 recites the limitation "the edge of said test strip" in line 21. There is insufficient antecedent basis for this limitation in the claim.

f) Claim 3: how does this claim further limit claim 1 as the area of the working electrode can only be the same or smaller or larger than area of the reference electrode?

g) Claim 3: which working electrode and which reference electrode are being referred to? Claim 1 requires the anode to have two working electrodes and two reference electrodes.

h) Claim 10 lists several acronyms that have not been defined in the specification;

i) Claim 12, line 4: -- in said separating layer -- should be inserted before "overlays";

j) Claim 14: are "screens" similar to layers?

k) Claim 15: if the reticular layer has been "processed" by surfactant is surfactant in the final product?

Note that dependent claims will have the deficiencies of base and intervening claims.

Allowable Subject Matter

7. Claim 1 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action.

8. The following is a statement of reasons for the indication of allowable subject matter: the combination of limitations in claim 1 requires "a reticular covering layer which covers said opening of said insulating layer wherein said reticular layer and said insulating layer form a sampling area from said reticular covering layer to the edge of said test strip." The covering layer (18) in Crismore et al. (US 6,270,637 B1) is not reticular (that is, netlike). It is a transparent or translucent window for "identifying sufficient dosing of the strip" (col. 4, ll. 41-47 and col. 2, ll. 15-19). Below the covering layer is a hydrophilic coating (25) and test reagent layer (12). In Carter et al. (US 5,628,890) the insulating layers (7, 11, and 13) define an enclosed sampling area, which does not extend to any edge of the test strip. None of the openings in the insulating layers have an opening end at an edge of the test strip.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

Art Unit: 1753

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1300.

Alex Noguera

Alex Noguera

01/26/2004

Primary Examiner

TC1753